DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

466 Fernandez Juncos Avenue
Puerta De Tierra
San Juan, Puerto Rico 00901-3223

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August 3, 2000

Warning Letter
SJN-00-19

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Jose Corripio
Chief Executive
Empresas La Famosa, Inc.
Road 866, Int # 865
Km. 12.1, Bo. Candelaria
P.O. Box 51968
Toa Baja, Puerto Rico 00950-1968

Dear Mr. Corripio:

From November 15 through December 13, 1999, Investigators Sonia Monges and Ileana B. Pettit from the Food and Drug Administration conducted an inspection at your juice and vegetable canning plant located at Road 866, Int. # 865, Km. 12.1, Bo. Candelaria, Toa Baja, Puerto Rico 00698. During that inspection, copies of your juice and vegetable product labels were obtained. Review of these labels and inspectional evidence finds that they are misbranded and adulterated within the meaning of Sections 402 and 403 of the Food, Drug and Cosmetic Act (the Act) and Title 21, Code of Federal Regulations (CFR), as follows:

The products identified as Econo brand "Nectar de Pera"; Sonny brand "Pear Nectar"; Grande brand "Nectar de Albaricoque", "Nectar de Melocoton", and "Nectar de Pera"; Amigo brand "Nectar de Pera", "Nectar de Melocoton", and "Nectar de Albaricoque"; Coloso brand "Fancy Pear Nectar"; and Mr. Special brand "Nectar de Pera" are misbranded under Section 403(I)(1) of the Act in that their labels fail to bear the common or usual name of the food in accordance with Title 21 Code of Federal Regulations (CFR) 102.33. The common and usual name for these beverages must indicate that one or more of the juices contained in these products is made from concentrate. Therefore, the statement of identity must contain a term indicating that fact, such as "from concentrate" or "reconstituted" (21 CFR 102.33(g)(1). Because Food Club brand "Ponche de Frutas" and Amigo brand "Ponche de Frutas" product do not make reference to specific juices in their names, the statement of identity for these two products does not have to include the term "from concentrate."

The above violations, which concern certain new labeling requirements, are not meant to be an all-inclusive list of deficiencies at your plant. Other labeling violations can subject

the food to legal action. It is your responsibility to assure that all of your products are labeled in compliance with all applicable statues enforced by FDA.

You have failed to register with the FDA as an acidified food processor as required by 21 CFR 108.25(c)(1); and failure to provide FDA with information on your scheduled processes for acidified foods including various brands of Piña Colada Mix as required by 21 CFR 108.25(c)(2).

In addition, you need to have a qualified person performing or supervising the container closure inspection for low-acid/acidified canned food (LACF) as required by 21 CFR 113.10.

You should take prompt action to correct these violations and prevent their future recurrence. Failure to promptly correct these violations may result in regulatory action without further notice. Possible actions include seizure and/or injunction.

Please notify this office in writing, within (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations. Copies of revised labels for the specified products should also be submitted. If corrective action cannot be completed within 15 days, state the reasons for the delay and the time at which the corrections will be completed.

Your written reply should be addressed to the Food and Drug Administration, attention: Carlos I. Medina, Compliance Officer, at 466 Fernandez Juncos Ave., Puerta de Tierra, San Juan, P.R. 00901. If you have any questions concerning the violations noted please contact the above named Compliance Officer at telephone number (787) 729-6894 ext. 2110.

Sincerely,

Wayne Matthews for
Mildred R. Barber
District Director